SCOTTISH HOSPITALS INQUIRY

Provisional Position Paper 6

The commissioning and validation process utilised for the Royal Hospital for Children and Young People and Department for Clinical Neurosciences

Purpose of the Paper

This Provisional Position Paper (PPP) has been produced to assist the Chair in addressing the Terms of Reference. It outlines the Inquiry team's current understanding of the process utilised to commission and validate the ventilation systems for the Royal Hospital for Children and Young People and the Department for Clinical Neurosciences (RHCYP/DCN).

Specifically, this PPP is concerned with the commissioning and validation of the Critical Care areas of the RHCYP/DCN. The Inquiry team understand that test results produced for the Critical Care department by IOM Consulting Ltd (IOM) were among the factors that informed the decision to delay opening the hospital.

In due course, the Chair is likely to be invited by the Inquiry Team to make findings in fact based on the content of this paper. It is open to any Core Participant, or indeed any other person holding relevant information, to seek to correct and/or contradict it by way of response to this paper. In considering those responses, and in taking forward its investigations, it is therefore possible that the Inquiry's understanding of matters set out in the paper may change, and so the position set out in this paper at this point remains provisional.

If it is the case that the Inquiry's understanding does change significantly, a revised edition of this paper may be published in due course.

While it is possible that the matters covered in this paper will be touched upon to a greater or lesser extent at a subsequent hearing held by the Inquiry – something that may also change the Inquiry's understanding of matters – this is not guaranteed, and if parties wish to address the issues dealt with in this paper, they are invited to do so now. If they do not do so, as noted above, the Chair is likely to be invited by the Inquiry Team to make findings in fact based on the content of this paper.

All responses to this paper received by the Inquiry will be published on its website as soon as possible after the deadline for responses has passed.

Contents

1. Introduction

1.1 The purpose of issuing this PPP is to set out the Inquiry team's provisional understanding of the process utilised to commission and validate the ventilation systems for the RHCYP/DCN. In particular, this PPP is concerned with how, during the lifecycle of the RHCYP/DCN project, the Board of NHS Lothian (NHSL) secured assurance and supporting evidence that:

- All necessary inspection and testing of the ventilation equipment had taken place;
- All key ventilation systems had been completed and functioned in accordance with contractual specifications and other applicable regulations, recommendations, guidance and good practice; and,
- Adequate information and training were provided to allow end-users effectively to operate and maintain key ventilation systems.

1.2 This PPP will address these matters with specific reference to the Critical Care areas of the RHCYP/DCN. The Inquiry team understand that test results produced for the Critical Care department by IOM were among the factors that informed the decision to delay opening the hospital.

1.3 The terms of this PPP reflect the Inquiry team's current understanding of the evidence it has available to it. If CPs, or any other party holding relevant information, wish to dispute, or supplement, what appears in the PPP, the Inquiry team invites them to do so.

1.4 Section 2 of this PPP identifies the project's contractual provisions relating to commissioning and validation. Section 3 provides a comparison of these provisions with the relevant terms in commissioning and validation guidance. Section 4 provides an overview of the commissioning and validation procedure utilised for the Critical Care areas of the RHCYP/DCN. Section 5 narrates the Inquiry team's understanding

of how test results for the Critical Care areas produced by IOM informed the decision to delay opening the hospital. Section 6 sets out the Inquiry team's provisional conclusions from the evidence set out in Sections 2 to 5. Section 7 sets out specific questions for CPs and requests for documents.

2. Contractual provisions for ventilation commissioning and validation

2.1 Contractual provisions for ventilation commissioning

2.1.1 On 12 and 13 February 2015, a Project Agreement was signed between the Board of NHSL and IHS Lothian (IHSL). IHSL were referred to in the Project Agreement as “Project Co”.

2.1.2 Schedule Part 6, Section 3 of the Project Agreement set out the Board’s Construction Requirements (BCRs). Paragraph 3.6.3 of the BCRs provided:

> “As part of the commissioning process, Project Co shall be responsible for demonstrating compliance with the requirements included within the Room Data Sheets.
>
> “For the avoidance of doubt, Project Co shall provide mechanical ventilation, comfort cooling and air conditioning to suit the functional requirements of each of the rooms in the Facilities. Irrespective of the ventilation requirements in Room Data Sheets, where rooms are clearly intended to be occupied and / or become internal spaces during design development and natural ventilation is not possible, mechanical ventilation and / or extract ventilation shall be provided as appropriate to suit the function of the space.”

2.1.3 The Inquiry team understand from the quoted section of the BCRs that the mechanical ventilation requirements in the Room Data Sheets were not to be used as part of the commissioning process. Rather, Project Co were to demonstrate compliance with the ‘functional requirements’ of the rooms. At this stage it is not clear from the contract what the functional requirements were in relation to ventilation. It is

also not clear where the functional requirements sit in relation to the terms of the contract quoted below. The Inquiry team invite CPs to assist on these points.

2.1.4 Paragraph 8 of the BCRs: 'Mechanical & Electrical Engineering Requirements', provided the following:

> "8.15 Commissioning and Testing
>
> "All buildings, services and equipment shall be commissioned by Project Co to ensure that all they [sic] are compliant with the quality and performance specifications, including manufacturer's recommendations, and that all systems operate to the Board's satisfaction.
>
> "Project Co shall as a minimum commission the Facilities in accordance with the 'Guidance to Engineering Commissioning' published by The Institute of Hospital Engineers (1995)."
>
> "…Project Co shall provide a comprehensive set of operation and Maintenance Manuals (in hard and electronic forms) for all installed and commissioned equipment…in accordance with the requirements in Clauses 17.18 (As built specification) and 18 (Post Completion Commissioning) of the Project Agreement.
>
> "Project Co shall provide such staff training as is deemed necessary by the Board details of training proposed shall be submitted to the Board as Reviewable Design Data for review by the Board in accordance with Schedule Part 8 (Review Procedure) and Clause 12.6 (Board's design approval) of the Project Agreement."

2.1.5 Clause 18 of the Project Agreement was titled 'Post Completion Commissioning'. Among other things under this clause (at clause 18.5), Project Co were to provide the Board with an 'operation and maintenance manual'. This was to

be in sufficient detail to allow the Board to plan for the safe and efficient operation of the facilities.

2.1.6 A final draft operation and maintenance manual was to be delivered on or before the day the Certificate of Practical Completion was issued by the IT. The principal version of the manual was to be delivered within the next 10 business days. The Certificate of Practical Completion for the RHCYP/DCN was issued on 22 February 2019.

2.1.7 The Certificate of Practical Completion was issued on the same date a 'Settlement Agreement and Supplemental Agreement' ("the Settlement Agreement") was signed between the Board of NHSL and IHSL. Although the Settlement Agreement created categories of work that were still to be completed as at 22 February 2019, and provided alternative deadlines for the operation and maintenance manuals relating to those works, the Inquiry team do not believe those manuals to be relevant to this PPP.

2.1.8 Schedule Part 10 of the Project Agreement included 'Completion Criteria' for the project. Under the heading 'Works Inspection, Testing and Acceptance Activities' the following text appeared:

> "2.1 Completion Criteria
> Project Co shall demonstrate that the following criteria (the "Completion Criteria") has been achieved:"
>
> "…2.1.4 All mechanical and electrical Plant and systems shall be tested, commissioned and operate satisfactorily in accordance with the specified design criteria, any manufacturers' operating requirements and the Room Data Sheets."

2.1.9 It is not clear to the Inquiry team how this provision was to be read with paragraph 3.6.3 of the BCRs, and exactly what this meant for the mechanical ventilation design criteria. The Inquiry team invite CPs to assist on this point.

2.1.10 Paragraph 4 of Schedule Part 10, 'Indicative Testing and Commissioning Documentation', provided a list of indicative test documentation expected to be provided to the Independent Tester (IT) as part of the Completion Criteria. This documentation included: "Air distribution systems in accordance with CIBSE [Chartered Institution of Building Services Engineers] Commissioning Code A". CIBSE Commissioning Code A is discussed at Section 3 of this PPP.

2.1.11 Clause 15.1 of the Project Agreement provided that the parties had: "appointed a suitably qualified and experienced consultant to act as the Independent Tester…upon the terms of the Independent Tester Contract."

2.1.12 The Independent Tester Contract was set out at Schedule Part 13 of the Project Agreement. Clause 2.1 of the Contract specifically provided that Project Co and the Board of NHSL jointly appointed the IT. Under Clause 2.2, the IT was to provide their services: "independently, fairly and impartially to and as between Project Co and the Board".

2.1.13 Among other things, the Contract provided that the IT was to:

- Undertake regular inspections during the testing and commissioning of the facilities, identifying any work that was not compliant with the BCRs, Project Co's Proposals, the Approved Reviewable Design Data (Approved RDD) and/or the Completion Criteria;
- issue a Certificate of Practical Completion;
- inspect and comment as required on the testing and commissioning as required by the Completion Process;
- Review the written Mechanical and Electrical engineering services testing and commissioning procedure;

- Undertake selective witnessing of the Mechanical and Electrical services testing and commissioning. It was anticipated this would apply to approximately 50% of the testing;
- Review 100% of all Mechanical and Electrical services test results.

2.1.14 Clause 17.12 of the Project Agreement provided that the IT was to issue a Certificate of Practical Completion to the Board and Project Co when he was satisfied that the facilities were complete in accordance with the Completion Criteria.

2.1.15 As discussed above, the Completion Criteria included the provision that all mechanical and electrical systems would operate satisfactorily in accordance with the Room Data Sheets". It is not currently clear how that provision was to be read with paragraph 3.6.3 of the BCRs.

2.1.16 Clause 18.4 of the Project Agreement provided: "On the completion of Project Co's Post-Completion Commissioning and the Board's Post Completion Commissioning the Independent Tester shall issue the Commissioning Completion Certificate."

2.2 **Contractual provisions for ventilation validation**

2.2.1 The Inquiry team have been unable to locate any specific contractual provisions for the validation of ventilation equipment in the RHCYP/DCN contract documents. It is not known if this reflected standard or accepted practice at the time.

3. Comparison of contractual provisions with guidance relating to ventilation commissioning and validation

3.1 Introduction

3.1.1 The Inquiry team acknowledge that the guidance referred to below was not written with privately financed or Non-Profit Distribution (NPD) projects, such as the RHCYP/DCN, in mind. It is therefore understood that aspects of the RHCYP/DCN contract will naturally diverge from that guidance.

3.1.2 However, with the exception of the Scottish Capital Investment Manual (SCIM) guidance on commissioning, the guidance discussed in this paper is that which is referred to in the RHCYP/DCN contract documents. Furthermore, as far as the Inquiry team are aware, this guidance formed best practice for commissioning and validation both at the time these activities were carried out at the RHCYP/DCN, and at the time of writing.

3.1.3 On the basis that the guidance discussed below formed best practice for all aspects of commissioning and validation, the Inquiry team understand it to be relevant in two senses. Firstly, it sets out the minimum standards by which ventilation equipment at the RHCYP/DCN was to be commissioned and validated. Secondly, it sets out the best practice relevant to all parties involved in the project, including NHSL. It is however acknowledged that, so far as the Inquiry team are aware, there was no actual provision for parties other than Project Co to adhere to the guidance set out below.

3.2 The definition and purpose of commissioning

3.2.1 Commissioning guidance referenced in the contract documents included the 'Guidance to Engineering Commissioning' published by The Institute of Hospital Engineering,[1] and ‘CIBSE Commissioning Code A: Air Distribution Systems’.

3.2.2 These guidance documents define commissioning in similar terms, as the advancement of an installation from static completion to full and satisfactory operation, complying fully with its design intent.

3.2.3 Scottish Health Technical Memorandum (SHTM) 03-01: ‘Ventilation for Healthcare Premises Part A – Design and validation’ is guidance also referred to in the contract, albeit as a design reference document as opposed to a commissioning document.

3.2.4 The version of this guidance that applied during the construction of the RHCYP/DCN was Version 2.0 dated February 2014. Unless otherwise specified, this is the version of SHTM 03-01 discussed in this PPP.

3.2.5 SHTM 03-01 is included here as it discusses commissioning, applies specifically to healthcare ventilation, and was published more recently than the guidance outlined above. The following definition of commissioning is provided: “Commissioning is the process of advancing a system from physical completion to an operating condition.” While this accords with the definition set out above, a later paragraph appears to widen the scope of commissioning when it states that: “The objective of commissioning is to ensure that the necessary performance and safety requirements are met.” While it is unclear what is meant by ‘safety requirements’, this could be read as overlapping with the Inquiry team’s understanding of validation, set out in paragraph 3.6.6 of this PPP.[2]

[1] In 1996 The Institute of Hospital Engineering became The Institute of Healthcare Engineering and Estate Management (IHEEM).
[2] In oral evidence provided to the Inquiry in May 2022, one of the Inquiry’s ventilation experts, Andy Poplett, was asked about the standard against which works should be checked during commissioning

3.2.6 SCIM guidance relating to commissioning is not referenced in the RHCYP/DCN contract documents, however that guidance is discussed here as it is described as setting out best practice principles for all investment projects.

3.2.7 The SCIM guidance described 'technical commissioning' as: "bringing the mechanical and electrical services and equipment in the building into use". This paragraph continued: "It will be the task of the contractor/design team to ensure that all services and equipment provided under the contract are operating according to the contract specification and be consistent with the user requirements in the Commissioning Master Plan." 'Commissioning Master Plan' (CMP) is not defined in the guidance, but the stated purpose of the CMP is to:

- "Identify key dates/phases for occupying or bringing the facility into use.
- Identify key tasks, targets and responsibilities.
- Identify a critical path for an integrated transfer of operations, addressing clinical need and functional interdependencies.
- Identify key briefing, design and construction interfaces.
- Identify key dates for selecting and ordering equipment.
- Identify any closures, security arrangements, site disposals, if relevant.
- Ensure that there is little or no disruption to patient services."

It is not clear to the Inquiry team what is meant by 'user requirements in the Commissioning Master Plan' and how this was to interact with the provision that equipment should perform to the contract specification.

3.2.8 The Inquiry team understand from the above paragraphs that the essential purpose of ventilation commissioning is to verify that the equipment is capable of delivering the performance criteria required by the design. Accordingly, it is understood that ventilation commissioning is not ordinarily concerned with verifying performance criteria against healthcare guidance, although this may be included

and validation. Mr Poplett advised: "It should be checked against the HTM, the design intent and the actual performance and contract." A transcript of Mr. Poplett's evidence can be found here: Transcript - Andrew Poplett - 10.05.2022 | Hospitals Inquiry. The quote just given can be found at pg 60.

within the scope of meeting the ‘safety requirements’ referenced in SHTM 03-01 or the ‘user requirements’ referenced in SCIM.[3]

3.2.9 The Introduction to the 'Guidance to Engineering Commissioning' states:

> “this document has been produced to define and prescribe the responsibilities appropriate to participants to the contract, the responsibilities which devolve onto design engineers to provide the necessary facilities within a design to enable commissioning to be properly completed, and finally to describe the recommended practical procedures for completing the on-site commissioning prior to handover or practical completion of engineering installations provided under main or sub-contracts.”

3.2.10 Paragraph 3.5 of the Guidance is titled ‘The Designer’s Role’. This paragraph includes the following text:

> “The design conditions required in various rooms and departments should be presented in the form of Room Data Sheets and Equipment Schedules, which should then form the basis of the commissioning data. The sheets should always contain such information as temperature, humidity, air change rate, noise levels, personnel and equipment loading, and any special room conditions such as pressure differentials with surrounding areas and filtration levels.
>
> “This information is not only essential for the design but also to form the basis on which the Commissioning Engineer must formulate his own test programme and assessment of results.
>
> “…It must be remembered that the purpose of testing and commissioning is to demonstrate that the installed plant and equipment complies with the requirements of the Design Intention Specification.”

[3] See footnote 2 above.

3.2.11 As discussed at paragraph 2.1.3 of this PPP, the BCRs appears to provide that Room Data Sheets were not to be used as part of the commissioning process. At this stage it is not clear what the requirements were in relation to ventilation, how these were presented, or whether this would be seen to comply with the Guidance. The Inquiry team invite CPs to assist on these points.

3.2.12 Nonetheless, in that the BCRs provide for the commissioning phase to verify equipment performance against a contractual standard, they appear to be consistent with the purpose of ventilation commissioning set out in the Guidance. The position under the Guidance therefore appears to align with that set out in the contract.

3.3 **The 'Guidance to Engineering Commissioning'**

3.3.1 Paragraph 6 of the 'Guidance to Engineering Commissioning' is titled 'Commissioning Programme'. This includes the text:

> "Commissioning should always be completed prior to the issue of a Certificate of Practical Completion".

3.3.2 The Project Agreement provided that the IT was to issue a Certificate of Practical Completion when he was satisfied that the facilities were complete in accordance with the Completion Criteria. The Completion Criteria included the provision that all mechanical and electrical systems would be tested, commissioned and operate satisfactorily in accordance with the specified design criteria and the Room Data Sheets. The position under the Guidance therefore appears to align with that set out in the contract.

3.3.3 Paragraph 6 of the Guidance also includes the following text:

> "It is essential that the Works Staff of the user authority should be involved in the final witnessing and demonstration as part of the familiarisation process."

‘Works Staff’ is not defined in the Guidance, however, from the context in which the term is used, it is understood to mean the party responsible for ongoing maintenance of the equipment.

3.3.4 The Inquiry team understand from the Services Contract dated 13 February 2015 between IHSL and Bouygues E&S FM UK Limited (BYES) that BYES were appointed to provide ongoing operation and maintenance of the equipment. BYES are therefore understood to be the ‘Works Staff’ for the RHCYP/DCN project.

3.3.5 At Schedule Part 5 of the Services Contract, paragraph 2.12: ‘Commissioning, Testing and User Training’, it is stated that:

> “Training is required to occur well in advance of building handover, during the testing and commissioning (T&C) phases. Bouygues E&S's operational staff will, following the T&C and on receiving the appropriate training will themselves, in the presence of the subcontractors, operate plant/equipment, carry out functional checks and test for alarm conditions till they are satisfied and confident for the handover.
>
> “The procurement contract, as necessary, should allow for training of key personnel on-site to acquaint them with the local environment. Certification of individual should be one of the training requirements to satisfy client and Bouygues E&S quality assurance requirements.
>
> “Full training needs to form part of the build costs package for ALL elements including M&E, fabric and external (e.g., BMS, Fire Alarm, Intruder Detection, CCTV, lifts passengers realise, Fagade panels /render, windows, doors, drainage, interceptors, etc).
>
> “All mechanical and electrical installations will be fully commissioned, tested in service and witnessed by appointed Bouygues E&S staff, test certificates and O&M manuals provided and FM staff trained and at operational condition prior

to handover from construction colleagues in order to achieve and demonstrate design performance."

3.3.6 The Inquiry team understand from the above that BYES were to witness the commissioning of all mechanical and electrical installations. The position under the Guidance therefore appears to align with that set out in the contract.

3.3.7 Paragraph 7 of the Guidance is titled 'Commissioning Reports'. The paragraph states:

"At the conclusion of the commissioning process, commissioning reports should be prepared for record purposes and future reference and possible inclusion in software programs. The preparation of commissioning reports should be the responsibility of either the Project Engineer or the Client's Commissioning Advisor and these reports should form part of the documents handed to the user at the conclusion of the contract.

"…Commissioning reports should report factually on the results achieved compared with the design duties. They should identify any particular problems which may require further work to meet user requirements.

"It must be appreciated that it is not the responsibility of any of the Contractors to prepare commissioning reports for general issue although it is known that some contractors prepare their own internal reports."

3.3.8 The Guidance defines the Project Engineer as the person nominated by the Client to monitor the installation of the engineering services related to a project. The Client's Commissioning Adviser was defined as the person nominated by the Client or the Client Body to advise whether the installation met the specified requirements.

3.3.9 For the RHCYP/DCN project, the Inquiry team understand that the responsibilities of 'Project Engineer' and 'Client's Commissioning Adviser', as defined

above, fell to the IT. It is understood that this was not entirely in accordance with the Guidance, as the IT acted on behalf of Project Co and the Board of NHSL. However, the Inquiry team acknowledge that the Guidance was not written with privately financed or NPD projects, where an IT is typically appointed, in mind.

3.3.10 Although not specifically referred to in the project documents as guidance for commissioning, SHTM 03-01 is also of note in referring to commissioning reports. SHTM 03-01 states:

> "Following commissioning and/or validation a full report detailing the findings should be produced. The system will only be acceptable to the client if at the time of validation it is considered fit for purpose and will only require routine maintenance in order to remain so for its projected life.
>
> "The report shall conclude with a clear statement as to whether the ventilation system achieved or did not achieve the required standard. A copy of the report should be lodged with the following groups:
>
> - the user department;
> - infection control (where required);
> - estates and facilities."

3.3.11 The Inquiry team are not aware of any provision in the RHCYP/DCN contract documents reflecting this recommendation.

3.3.12 Part II of the 'Guidance to Engineering Commissioning' provides:

> "The purpose of Part II of this manual is to establish, and conform to, a systematic set of procedures which must be followed in the testing, balancing, adjusting and setting to work of all mechanical and electrical services, equipment and systems installed as part of the contract.

> "The procedures outlined are applicable to the final examination, setting to work and commissioning of all air, hydraulic and electrical services installed."

3.3.13 At Paragraph 20.3: 'Aspects of Commissioning – Ventilation Systems', Part II of the guidance goes on to state:

> "…Design Requirements
>
> "The designers attention is drawn to the requirements of the CIBSE Commissioning Code, Series A, Air Distribution. The data given in the following paragraphs is a summary of the major points of this guide but it is not comprehensive; it is intended to provide an aide memoire only."

3.3.14 The Inquiry team understand from the above that CIBSE Commissioning Code A is considered to be a 'systematic set of procedures which must be followed' when commissioning ventilation systems.

3.4 CIBSE Commissioning Code A

3.4.1 According to CIBSE Commissioning Code A, the Code sets out generally to inform on 'what should be done', whereas manuals published by the Building Services Research and Information Association (BSRIA) inform on 'how it should be done'.

3.4.2 The Inquiry team understand from CIBSE Commissioning Code A that an essential factor of ventilation commissioning is measuring air volume flow rates and comparing these with the flow rates required by the design.[4]

3.4.3 CIBSE Commissioning Code A goes on to discuss pressure differentials. The Code sets out a procedure suggested as suitable for the commissioning of typical

[4] In oral evidence provided to the Inquiry in May 2022, Mr Poplett advised that volume flow rates are required to calculate air changes per hour. See pg 17 of the transcript of Mr. Poplett's evidence.

ventilation systems designed to produce pressure regimes within a space. Once certain mechanical operations have been completed, this procedure includes the following steps:

> "Measure and record the pressure differentials between all adjacent spaces using a suitable instrument and compare the measurements with the specified design requirements.
>
> "At this stage the results obtained should be submitted to the designer or accepting authority.
>
> "…Once acceptable conditions are obtained, it is imperative to record final balance figures including air volume flow rates and pressure differentials. These should also be verified by the accepting authority."

3.4.4 The RHCYP/DCN contract does not include provisions relating to the specifics of how ventilation commissioning should be carried out. For example, no detail is provided with respect to how air volume flow rates or air pressure differentials should be measured and/or compared with the design specification. However, as part of a provision to supply documentation to the IT, the Project Agreement included an expectation that Project Co would provide commissioning documentation in accordance CIBSE Commissioning Code A. The Inquiry therefore understand that the contract expected commissioning to be carried out in a way that reflected the specifics of 'what should be done' in the Code. The contract therefore appears to align with the detail of the Code set out above.

3.4.5 Section A5 of the Code outlines recommendations concerning witnessing. According to the Code, the objective of the witnessing stage is to enable the witnessing authority to establish a level of confidence in the commissioning results being presented. The Code provides that, unless the designer has specifically called for all commissioning aspects to be witnessed, an assessment of a proportion of results should satisfy this requirement.

3.4.6 As discussed above, the Services Contract between IHSL and BYES intended that BYES were to witness the commissioning of all mechanical and electrical installations. The IT contract also provided that the IT would undertake selective witnessing of the Mechanical and Electrical services testing and commissioning. It was anticipated this would apply to approximately 50% of the testing. The position under the Code therefore appears to align with that set out in the contract.

3.4.7 The Code states that: “appropriate documentation should be provided by the commissioning specialist for the witnessing authority to countersign to confirm details of the tests observed and that the results are within the specified tolerances. When the documentation is completed, the system can be deemed to be commissioned in accordance with this Code.”

3.4.8 The IT contract provided that the IT would review 100% of all Mechanical and Electrical services test results. This is understood to include all the ventilation commissioning test results. The position under the Code therefore appears to align with that set out in the contract.

3.5 **SCIM ‘Commissioning Process’**

3.5.1 Paragraph 4.15 of the SCIM guidance, ‘Site Visits and Training’, provided: “As the facility comes closer to completion, site visits for staff training and familiarisation should be organised by the [Client’s] Commissioning team well in advance with the contractor and PM [Project Manager]… The run up to Handover is often frenetic and has many competing priorities; however the importance of on-site operational and maintenance training and documentation cannot be underestimated. A facility handover cannot occur without fit-for-purpose and safe operation”.

3.5.2 Paragraph 4.16 of SCIM, ‘Technical Commissioning’, elaborated:

> "It will be the responsibility of the Project Manager to ensure that the contractor draws up a full programme of technical training and demonstrations... Dates and times of these will be agreed with the Commissioning Manager, who will arrange for the relevant personnel from the users of the facility to be in attendance, so that they can understand how the facility/ equipment operates.
>
> "It will be the responsibility of the contractor, under the terms of the contract, to ensure that all technical manuals, Health & Safety, CDM [Construction Design Management] and literature relating to the operation and maintenance of the facility, equipment and plant are passed to the Commissioning manager for review, then final submission, to the format and timetable agreed in the Commissioning Master Plan. User manuals, in 'non technical speak', are required to support staff to use the facility safely and effectively. The Project Manager must ensure that this is done."

3.5.3 Paragraph 8.15 of the BCRs stated: "Project Co shall provide such staff training as is deemed necessary by the Board details of training proposed shall be submitted to the Board as Reviewable Design Data".

3.5.4 As discussed at paragraphs 3.3.5 and 3.3.6 of this paper, the Services Contract between IHSL and BYES also intended that BYES would be trained to use the equipment during the testing and commissioning phase prior to handover.

3.5.5 Under Clause 18 of the Project Agreement, Project Co were also to provide the Board with an operation and maintenance manual in sufficient detail to allow the Board to plan for the safe and efficient operation of the facilities.

3.5.6 A final draft operation and maintenance manual was to be delivered on or before the day the Certificate of Practical Completion was issued by the IT. The principal version of the manual was to be delivered within the next 10 business days. The position under the SCIM guidance therefore appears to align with that set out in the contract.

3.6 The definition and purpose of validation

3.6.1 The Inquiry team are currently unaware of any guidance specifically referenced in the RHCYP/DCN contract for validating the ventilation equipment. The only guidance known to be relevant to validation is SHTM 03-01 Part A. SHTM 03-01 is referenced throughout the contract documents for the project, but only in relation to the design, installation, cleaning, and infection prevention and control aspects of the ventilation systems.

3.6.2 In the absence of specific evidence as to contractual provisions, the Inquiry has had regard to SHTM 03-01 Part A. As the preface to that document makes clear, the purpose of the SHTMs is: "give comprehensive advice and guidance on the design, installation and operation of specialised building and engineering technology used in the delivery of healthcare…Healthcare providers have a duty of care to ensure that appropriate engineering governance arrangements are in place and are managed effectively. The Engineering Scottish Health Technical Memorandum series provides best practice engineering standards and policy to enable management of this duty of care."

3.6.3 The SHTM defines validation as:

> "A process of proving that the system is fit for purpose and achieves the operating performance originally specified. It will normally be a condition of contract that 'The system will be acceptable to the client if at the time of validation it is considered fit for purpose and will only require routine maintenance in order to remain so for its projected life.'"

3.6.4 To the best of the Inquiry team's knowledge, the contract for the RHCYP/DCN project did not contain such a clause nor any clause relating to the validation of ventilation systems. No further comparison can be made between validation guidance and the contract, as the Inquiry team have been unable to locate any contract provisions for the validation of ventilation equipment.

3.6.5 The SHTM continued by stating:

> "Validation differs from commissioning in that its purpose is to look at the complete installation from air intake to extract discharge and assess its fitness for purpose as a whole. This involves examining the fabric of the building being served by the system and inspecting the ventilation equipment fitted as well as measuring the actual ventilation performance."

3.6.6 The Inquiry team understand from the above paragraphs that the essential purpose of ventilation validation is to verify that the system as a whole is fit for purpose. This is understood to mean that validation is, at least to some extent, concerned with verifying equipment performance criteria against healthcare guidance.

3.7 **SHTM 03-01**

3.7.1 At paragraph 1.39, SHTM 03-01 discusses the design and validation process, with specific reference to a 'specialised ventilation system'. At paragraph 7.2, the SHTM includes the text:

> "The following departments will require a degree of specialised ventilation.
>
> "...critical areas and high dependency units of any type"

3.7.2 Paragraph 7.4 of SHTM 03-01 stated:

> "It is not possible within this existing document to give definitive guidance for every healthcare specific ventilation application. Additional detailed guidance may be issued in due course in the form of supplements."

The Inquiry team are not aware of any detailed supplement relating to Critical Care areas that (i) existed at the time the RHCYP/DCN was constructed, or that (ii) exists at the time of writing.

3.7.3 Section 8 of SHTM 03-01 is titled 'Validation of specialised ventilation systems'. When defining validation, this section stated:

> "It is unlikely that 'in house' staff will possess the knowledge or equipment necessary to validate critical ventilation systems such as those serving operating suites, pharmacy clean rooms and local exhaust ventilation systems. Validation of these systems should therefore be carried out by a suitably qualified independent Authorised Person appointed by the NHS Board. It is anticipated that training in the validation of specialised healthcare ventilation systems for independent Authorised Persons will become available during the life of this SHTM."

3.7.4 SHTM 03-01 continues to discuss validation in greater detail, but only in relation to Ultra Clean Ventilation (UCV) suites.

3.7.5 The Inquiry team understand from the information set out above that, so far as there was any validation guidance or best practice available at the time the RHCYP/DCN was constructed, all areas within a hospital requiring specialised ventilation were recommended for validation by an independent party appointed by the Health Board. The areas requiring specialised ventilation included Critical Care areas.

3.7.6 It is of note that the updated version of SHTM 03-01 Part A (Interim Version 3, dated February 2022) amends this position to provide that: "All new and refurbished ventilation systems should be independently validated prior to acceptance by the client."

3.7.7 From the information set out above, and evidence heard by the Inquiry,[5] the Inquiry team understand that activities to validate ventilation equipment would be expected to identify the types of divergences between performance criteria and healthcare guidance that IOM identified immediately prior to the scheduled opening of the RHCYP/DCN in July 2019. IOM's involvement in the project is discussed more fully at Section 5 of this PPP.

[5] See footnote 2 and pg 60 of the transcript of Mr. Poplett's evidence.

4. Overview of the ventilation commissioning and validation procedure for Critical Care

4.1 **Table 1**

4.1.1 Table 1 below sets out an overview of the commissioning and validation process for the Critical Care bedrooms at the RHCYP/DCN. Table 1 sets out the following information:

- the ventilation equipment relevant to each area;
- what party commissioned/validated the relevant area prior to IOM's involvement in the project;
- what party witnessed/approved this commissioning/validation; and
- the dates these activities occurred.

4.1.2 Table 1 is followed by a fuller discussion of its contents. Section 5 of this PPP narrates the Inquiry team's understanding of how test results produced by IOM for these Critical Care areas informed the decision to delay opening the hospital.

Table 1

Location	Room Reference	Room Number	Relevant Equipment	Commissioned By/On	Witnessed By/On	Approved By/On	Validated By/On
Critical Care	HDU 4 bed bay	1-B1-009	Air Handling Unit (AHU) 04-06	H&V Commissioning Ltd (H&V) AHU Extract: 24/10/18 AHU Supply: 30/10/18 No Room Pressure Differentials (RPD)	Witnessing pages blank.	AHU approved by Arcadis: 18/02/19	No record
Critical Care	HDU 4 bed bay	1-B1-031	AHU 04-06	H&V Same commissioning documents as above	As above	As above	No record
Critical Care	HDU 4 bed bay	1-B1-063	AHU 04-06	H&V Same commissioning documents as above	As above	As above	No record
Critical Care	HDU single bed cubicle	1-B1-037	AHU 04-06	H&V Same commissioning documents as above	As above	As above	No record

Critical Care	NNU 3 cot bay	1-B1-065	AHU 04-06	H&V Same commissioning documents as above	As above	As above	No record
Critical Care	NNU single cot cubicle	1-B1-075	AHU 04-06	H&V Same commissioning documents as above	As above	As above	No record
Critical Care	Single bedroom	1-B1-020	AHU 04-06	H&V Same commissioning documents as above	As above	As above	No record
Critical Care	Single bedroom	1-B1-021	AHU 04-06	H&V Same commissioning documents as above	As above	As above	No record

Critical Care	Single bed isolation room	1-B1-016	AHU 04-06 & Isolation Extract Fan (IEF) 06	H&V Same commissioning documents as above. IEF commissioned 06/06/18.	Witnessing pages blank for AHU. IEF witnessed by NHSL, BYES: 02/08/18	As above for AHU. IEF approved by Arcadis: 09/11/18	Validator(s) to be confirmed. See footnote. Validation approved on 06/06/19 by Multiplex (MPX), Mercury and Arcadis. [6]
Critical Care	Single bed isolation room	1-B1-017	AHU 04-06 & IEF05	H&V Same commissioning documents as above. IEF commissioned on 03/07/2018.	Witnessing pages blank for AHU. IEF witnessed by NHSL & BYES on 02/08/18	As above for AHU. No record of IEF approval.	Validator(s) to be confirmed. See footnote. Validation approved on 06/06/19 by Multiplex (MPX), Mercury and Arcadis. [7]

[6] See para 4.2.44 of this PPP.
[7] See para 4.2.44 of this PPP.

Critical Care	Single bed isolation room	1-B1-026	AHU 04-06 & IEF04	H&V Same commissioning documents as above. IEF commissioned on 16/02/2018.	Witnessing pages blank for AHU. IEF witnessed by NHSL & BYES on 02/08/18	As above for AHU. No record of IEF approval.	Validator(s) to be confirmed. See footnote. Validation approved on 06/06/19 by Multiplex (MPX), Mercury and Arcadis. [8]
Critical Care	Single bed isolation room	1-B1-036	AHU 04-06 & IEF03	H&V Same commissioning documents as above. IEF commissioned on 16/02/18	Witnessing pages blank for AHU. IEF witnessed by Mercury and MPX on 14/06/18	As above for AHU. No record of IEF approval.	Validator(s) to be confirmed. See footnote. Validation approved on 06/06/19 by Multiplex (MPX), Mercury and Arcadis. [9]

[8] See para 4.2.44 of this PPP.
[9] See para 4.2.44 of this PPP.

4.2 Further discussion on Table 1

4.2.1 The Project Agreement provided for Project Co to produce Room Data Sheets for all rooms and areas in the hospital including the data contained in an 'Environmental Matrix'.

4.2.2 The Environmental Matrix included environmental information relevant to the ventilation of different spaces in the hospital. Such information included the type of ventilation serving a space, the number of air changes per hour provided, and the air pressure differentials between spaces.

4.2.3 Previous PPPs have been produced setting out the Inquiry team's understanding of how an earlier version of this Environmental Matrix was shared with prospective tenderers during the procurement process for the RHCYP/DCN project.

4.2.4 At this stage the Inquiry team believe that the Environmental Matrix shared with tenderers specified environmental information that was potentially inconsistent with published guidance, namely SHTM 03-01 – which outlines ventilation requirements in a hospital.

4.2.5 The exact purpose and status of the Environmental Matrix shared with tenderers is still unclear. These matters were explored in greater detail at the hearing in April 2023 and the findings of the Inquiry will follow in due course.

4.2.6 The Environmental Matrix was defined in the Project Agreement as setting out the: "room environmental condition requirements of the Board required within each department / unit / space / area…(as varied, amended or supplemented from time to time…)".

4.2.7 The Environmental Matrix was included in the Project Agreement as Reviewable Design Data (RDD). This meant the terms of the Environmental Matrix were not fully agreed between the parties when the Project Agreement was signed in

February 2015, and that the document was subject to further review and approval by IHSL and the Board of NHSL.

4.2.8 The development of the Environmental Matrix as RDD is addressed in a separate PPP by the Inquiry team. For the purposes of this PPP, it is understood that the Environmental Matrix was to be finalised before Room Data Sheets were submitted as RDD. As far as the Inquiry team are aware, no final Room Data Sheets were produced for the project, and the majority of the final environmental information agreed by NHSL and Project Co was contained in Version 11 of the Environmental Matrix, dated 25 October 2017.

4.2.9 While the Environmental Matrix was being developed as RDD, the Board of NHSL and IHSL became engaged in a design dispute involving the design of the ventilation to some four-bed rooms in the hospital. Evidence indicates this related to differing interpretations of the pressure regime requirements for the four-bed rooms.

4.2.10 In late 2017 and early 2018, the Board of NHSL also identified further aspects of the ventilation design that were potentially non-compliant with SHTM 03-01. The resolution to these matters and the four-bed ventilation dispute was eventually agreed between the parties in the Settlement Agreement dated 22 February 2019. It does not appear that an updated version of the Environmental Matrix was produced to incorporate these resolutions.

4.2.11 Therefore, for the purposes of this PPP, it appears to the Inquiry team that the final contractual specification for ventilation at the RHCYP/DCN was constituted of:

- the environmental information in Version 11 of the Environmental Matrix dated 25 October 2017; as amended by
- the environmental information agreed by the Settlement Agreement dated 22 February 2019.

4.2.12 In light of the Inquiry team not having seen any final Room Data Sheets for the project, and the view that the most up-to-date environmental information for the project comes from version 11 of the Environmental Matrix read in conjunction with the Technical Schedule in Settlement Agreement 1, it is not clear to the Inquiry team how paragraph 3.6.3 of the BCRs applied to the project in practice. The Inquiry team invite CPs to assist on this point.

4.2.13 Furthermore, paragraph 3.6.3 of the BCRs goes on to state that the mechanical ventilation requirements in the Room Data Sheets were not to be used as part of the commissioning process. Rather, Project Co were to demonstrate compliance with the 'functional requirements' of the rooms. While this provided for the commissioning phase to verify equipment performance against a contractual standard, which appears to be consistent with the purpose of ventilation commissioning set out in the Guidance, it is not clear what design conditions the mechanical ventilation systems were to actually meet during commissioning. The Inquiry team invite CPs to assist on this point.

4.2.14 The air change rates and room pressure differentials of each Critical Care bedroom were dictated by the Air Handling Unit (AHU) serving that room. In certain bedrooms noted in Table 1, the air change rate and room pressure differentials were also dictated by separate Isolation Extract Fans (IEFs).

4.2.15 Each AHU and IEF was commissioned by H&V Commissioning Ltd (H&V).

4.2.16 The Critical Care bedrooms were all served by AHU 04-06. That AHU was commissioned on 24 and 30 October 2018. The separate IEFs were commissioned between February and July 2018. However it appears the Settlement Agreement of 22 February 2019 finalised the specification for these rooms, and required an alteration to the design of the four-bed rooms. It is therefore not clear to the Inquiry team how the earlier commissioning sits in relation to the later agreed specification. The Inquiry team invite CPs to assist on this point.

4.2.17 The Project Agreement provided that the IT was to issue a Certificate of Practical Completion when he was satisfied that the facilities were complete in accordance with the Completion Criteria. The Completion Criteria included the provision that all mechanical and electrical plant and systems would be tested, commissioned and operate satisfactorily in accordance with the specified design criteria and the Room Data Sheets. These provisions were in accordance with the recommendations in the 'Guidance to Engineering Commissioning'.

4.2.18 However, in practice, the Certificate of Practical Completion for the RHCYP/DCN was issued on 22 February 2019. This was the same date the Settlement Agreement referred to above was signed. It therefore appears to the Inquiry team that the commissioning of the ventilation equipment cannot have been completed prior to the Certificate of Practical Completion being issued. This is because the specifications against which certain equipment was to be verified were signed off on the same day the Certificate was issued. Accordingly it appears that, in practice, the Certificate of Practical Completion was not issued in accordance with the Guidance, however the Inquiry team invite CPs to assist on this point.

4.2.19 Under the Project Agreement, the IT was also to issue a Commissioning Completion Certificate on the completion of Project Co's Post-Completion Commissioning and the Board's Post Completion Commissioning. The Commissioning Completion Certificate for the RHCYP/DCN was issued on 22 February 2019, the same date the Settlement Agreement referred to above was signed.

4.2.20 The Settlement Agreement included a 'Joint Completion Programme' setting out a timetable for the commissioning tasks still to be completed as at 22 February 2019. It therefore appears to the Inquiry team that, in practice, the commissioning of the ventilation equipment cannot have been completed prior to the Commissioning Completion Certificate being issued, however the Inquiry team invite CPs to assist on this point.

4.2.21 Project Co were expected to provide commissioning documentation to the IT in accordance CIBSE Commissioning Code A. Where pressure differentials between areas are intended by a ventilation design, CIBSE Commissioning Code A recommends measuring and recording these between all adjacent spaces, and comparing the measurements with the specified design requirements. The Code states that, once acceptable conditions are obtained, it is imperative to record final balance figures including air volume flow rates and pressure differentials. These should then be verified by the accepting authority.

4.2.22 Although ventilation supply and extract data for the AHU and IEFs was measured and recorded, it does not appear the same was done for room pressure differential data. As far as the Inquiry team understand, room pressure differentials were only recorded by H&V for the AHUs that served operating theatres. It appears that no room pressure differentials were recorded, witnessed or approved for the rooms in Table 1. This was despite the design for these areas having pressure requirements relative to adjacent spaces. In practice it therefore appears that the provisions set out in the above paragraph were not achieved, however, the Inquiry team invite CPs to assist on this point.

4.2.23 The IT contract provided for the IT to review 100% of all Mechanical and Electrical services test results. This was in alignment with the recommendation in CIBSE Commissioning Code A that commissioning documentation should be provided for the witnessing authority to countersign to confirm test results. On the basis that no room pressure differentials were recorded, witnessed or approved for the rooms in Table 1, it appears to the Inquiry team that these terms of the contract and the Code were not met. It is not known why the IT did not request this data. It is also not clear why the IT issued the Certificate of Practical Completion without this data being measured and approved. The Inquiry team invite CPs to assist on this point.

4.2.24 The 'Guidance to Engineering Commissioning' provided that commissioning reports should be prepared at the conclusion of the commissioning process by the

person monitoring the installation of the engineering services, or the person advising whether the installation met the specified requirements. For the RHCYP/DCN project, the Inquiry team understand that these responsibilities fell to the IT. The only commissioning documentation seen by the Inquiry team was produced by H&V. It is understood this was then approved by the IT. It is not known if this process reflects standard or accepted practice.

4.2.25 SHTM 03-01 recommended that, following commissioning and/or validation, a full report detailing the findings should be shared with infection control (where required). The Inquiry team are not aware of any provision in the RHCYP/DCN contract documents reflecting this recommendation, however the Inquiry team are aware that in practice a 'Theatre Ventilation Validation Checklist' for one of the operating theatres at the hospital was shared with infection control prior to IOM's involvement with the project. This is discussed at Section 5 of this PPP.

4.2.26 The commissioning test reports for AHU 04-06 were approved by Arcadis, the IT, on 18 February 2019. On the basis the commissioning reports show that tests for AHU 04-06 were not witnessed, it is not known why the IT approved these reports. It is also not clear why the IT issued the Certificate of Practical Completion on this basis.

4.2.27 The Inquiry team cannot locate commissioning test report approval for any of the IEFs other than for IEF06, which was approved by Arcadis on 9 November 2018. On the basis that these reports were not approved, it is not known why the IT did not request the outstanding information for approval or why the Certificate of Practical Completion was issued without this information being approved.

4.2.28 The Inquiry team understand that measuring air volume flow rates and comparing these with the flow rates required by the design is a crucial aspect of commissioning, as evidenced by CIBSE Commissioning Code A, SHTM 03-01 and

evidence heard by the Inquiry. The Inquiry team also understand that volume flow rates are required to calculate air changes per hour.[10]

4.2.29 Irrespective of the purpose of commissioning to verify equipment performance against design criteria, the Inquiry team therefore understand that the commissioning phase may have offered an opportunity for the parties involved in commissioning to have sight of design and performance criteria that was later identified by IOM as diverging from healthcare guidance.

4.2.30 It is not clear what individual(s) reviewed test results on behalf of the IT for the rooms in Table 1. The Inquiry team invite CPs to assist on this point. An 'Independent Tester Services' proposal seen by the Inquiry team names John Edwards as having the appropriate capacity to deliver the IT services in relation to Mechanical & Electrical engineering. The proposal also states that Mr. Edwards is a qualified Authorising Engineer for ventilation services. The Inquiry team therefore understand that the IT may have possessed a certain level of awareness and expertise with respect to HTM and SHTM standards. The Inquiry team accordingly understand that this may have offered the IT a greater opportunity to identify design and performance criteria that diverged from healthcare guidance.

4.2.31 The Services Contract between IHSL and BYES intended that all mechanical and electrical installations would be fully witnessed by BYES. The IT contract also provided that the IT would undertake selective witnessing of the Mechanical and Electrical services testing and commissioning. It was anticipated this would apply to approximately 50% of the testing. These provisions complied with recommendations in CIBSE Commissioning Code A. However in practice it does not appear that commissioning tests for AHU 04-06 were witnessed. Although the IT does not appear to have witnessed the testing for AHU 04-06, it is not known whether the IT otherwise complied with the witnessing provision in the IT contract. Commissioning tests for the IEFs were witnessed.

[10] See pg 17 of the transcript of Mr. Poplett's evidence and Health Facilities Scotland, 'Scottish Health Technical Memorandum 03-01 Ventilation for healthcare premises Part A – Design and validation', (February 2014), para 8.33.

4.2.32 Paragraph 8.15 of the BCRs stated: “Project Co shall provide such staff training as is deemed necessary by the Board details of training proposed shall be submitted to the Board as Reviewable Design Data”. This provision facilitated the recommendation in SCIM commissioning guidance that staff training and familiarisation should be organised prior to handover.

4.2.33 The Inquiry team have not been able to locate the ‘details of training proposed’ that this paragraph of the BCRs provided to be submitted as RDD. However, the Inquiry team have had sight of a letter dated 1 April 2019 from the Board of NHSL to Gordon James of Health Facilities Scotland (HFS).

4.2.34 The letter indicates it was written in response to a letter from HFS dated 8 March 2019. That letter of 8 March stated:

> “We have been learning lessons from projects over the past few years, relating to the implications for safety and efficacy of engineering systems, of failure to ensure thorough discharge of client duties in construction projects. In response to recent issues where the financial and safety issues for the service have been very significant, Scottish Government has asked that we seek assurances about the management of projects in progress and those which have been recently completed, and provide a report for the Director for Health Finance.
>
> …
>
> Lessons learned from recent projects:
>
> - Water systems contaminated by bacteria during construction and not managed suitably after being filled, allowing biofilm to grow, incurring costs and management resource for the life of the system.
> - Pre commissioning checks not fully carried out, recorded and handed over, allowing shortcomings to pass unchallenged.
> - Commissioning of services not carried out properly leading to maintenance, energy and rectification costs over the life of the systems,

equipment (thermostatic valves and taps, controls etc) not set up and set to work prior to handover.

- Safe access not provided for maintenance and replacement of services in accordance with legal requirements, entailing health and safety risks for staff and contractors over the life of the building.
- Routine maintenance not implemented, entailing deterioration of safety critical systems and health and safety risks for staff, patients and visitors, as well as increased running costs.

It has become clear that, although much of the above is the responsibility of the contractor, the management of the contractor and any supervisory contractor by the client is essential to ensure the desired quality of the completed project. It proves complex and costly, or impractical to pursue the contractor for rectification if the client role has not been adequately discharged.

Can you therefore please provide evidence of:

…

4. How the Board is assured that its staff and appropriate contractors are adequately trained to ensure engineering systems are managed and operated competently"

4.2.35 In response to this request, NHSL's letter of 1 April provided:

"…IHSL are contractually obliged to provide sufficient staff with the requisite level of skill and experience for the provision of the maintenance and operation of the Engineering Systems.

"The Board is entitled to review training records and training programs at its discretion and has undertaken this exercise in preparation for the handover of the facilities... NHSL has reviewed the training records to check that appropriate training and certification is in place."

> "…The wider clinical staffing of the hospital has been provided with familiarization training of the site including the user interfaces for engineering systems where appropriate to their roles. Additional guidance on these user interfaces is being included in the Building User Guide for the hospital."

4.2.36 Emails from July 2019 also indicate that NHSL were asked to provide certain documentation to NHS National Services Scotland (NHS NSS). These emails date from after the decision was taken to delay opening the RHCYP/DCN.

4.2.37 An 'NSS Schedule Tracker' attached to one of these emails sets out that 'formal training records for all NHSL and FM [Facilities Management] Contractor staff' were requested by NHS NSS. A comment for this entry on the schedule reads: "… awaiting information. Training given by MPX [Multiplex] to BYES and to NHS by either MPX or BYES."

4.2.38 The Inquiry team understand from the information set out in paragraphs above that:

- BYES were appointed to provide ongoing operation and maintenance of the equipment.
- BYES were trained to operate and maintain the equipment while witnessing equipment tests during the commissioning phase;
- training was subsequently given to NHSL by BYES or MPX;
- NHSL secured assurance that adequate operation and maintenance training were provided by reviewing 'training records' provided by Project Co;
- NHSL were satisfied from these reviews that the appropriate training and certification was in place; and,
- wider clinical staffing of the hospital were provided with familiarization training for engineering systems where this was appropriate to their roles.

4.2.39 In light of the understanding that BYES did not witness the commissioning of AHU 04-06, the Inquiry team are consequently of the understanding that no party

may have been trained to operate and maintain this equipment. Accordingly, the Inquiry team understand that the staff training recommendation in SCIM commissioning guidance may not have been achieved with respect to AHU 04-06, however the Inquiry team would invite the assistance of CPs on these points.

4.2.40 Under Clause 18 of the Project Agreement, Project Co were to provide the Board with an ‘operation and maintenance manual’. This was to be in sufficient detail to allow the Board to plan for the safe and efficient operation of the facilities.

4.2.41 A final draft operation and maintenance manual was to be delivered on or before the day the Certificate of Practical Completion was issued by the IT. The principal version of the manual was to be delivered within the next 10 business days. These provisions aligned with the recommendation made in SCIM commissioning guidance that operation and maintenance manuals should be provided by the contractor for review, then final submission, to the client.

4.2.42 The Inquiry team have not been able to locate the final draft or principal operation and maintenance manuals for the project referenced in Clause 18.5. However Multiplex have submitted files to the Inquiry that include ‘O&M [Operation & Maintenance] manuals’ for specific items of ventilation equipment. These include manuals for AHUs and fans, ostensibly dating to January 2017 and May 2018 respectively.

4.2.43 With respect to the ventilation equipment, it is not currently clear whether these are all the required manuals for operation and maintenance. It is also not clear if/when these manuals were submitted to NHSL and approved. It is therefore not clear whether recommendations made in SCIM guidance were met. The Inquiry team invite CPs to assist on this point.

4.2.44 Documents headed with the Multiplex logo and titled ‘Isolation Room Ventilation Validation Checklist’ have been seen by the Inquiry team for each of the single bed isolation rooms in Table 1. These documents conclude with the statement:

"Isolation Room validated in accordance with SHPN [Scottish Health Planning Note] 04 Supplement 1".

4.2.45 SHPN 04 Supplement 1 provides guidance on the facilities required for isolating patients on acute general wards. The guidance includes an Appendix titled 'Acceptance testing of isolation suite'. That Appendix includes the following text:

> "System operating standard
>
> The suite will be considered fit for purpose if, with the ventilation system operating and all doors closed, the following parameters are achieved:
>
> • a positive pressure of between 10 and 12 Pascals between the entry lobby and the corridor;
> • the patient's room has an air change rate of at least 10 per hour;
> • the en-suite room is at a negative pressure with respect to the patient's room;
> • a failure of either the supply or extract fan will be indicated at a designated nurse station and the estates department."

4.2.46 SHPN 04 Supplement 1 is therefore understood to be concerned with measuring equipment performance against healthcare guidance. Validating in accordance with SHPN 04 Supplement 1 would therefore accord with the Inquiry team's understanding of validation set out at paragraph 3.6.6 of this PPP.

4.2.47 The 'Isolation Room Ventilation Validation Checklist' documents contain air change rate and room pressure differential data that was approved by Multiplex, Mercury and Arcadis on 6 June 2019. Mercury were a sub-contractor of Multiplex for the Mechanical, Electrical & Public Health Services at the RHCYP/DCN. It is not clear from the face of the documents whether Multiplex, Mercury and Arcadis were the parties that carried out the validation of these areas, or whether they approved the validation carried out by another party. In these documents an H&V engineer is

named as providing the filtration data, and an RSK Environment Ltd Director is named as providing the air permeability results, but no other parties are named. A 'Method Statement for H&V Commissioning Services Ltd' regarding 'Validation of Theatre Suites & Isolation Rooms' has been seen by the Inquiry team. This document features the text: "All validation detail and pass criteria set out in afore mentioned documents SHTM 03-01 & SHPN 04 supplement 1". This document may suggest that H&V provided the validation, as well as the commissioning, of these rooms. The Inquiry team invite CPs to assist on this point.

4.2.48 The Inquiry team have seen 'Validation Reports' produced by Medical Air Technology Ltd (MAT) for each of the hospital's UCV theatres. Each report states that it: "defines those tests which are to be carried out in order to verify that the installed UCV System performs in accordance with the requirements of SHTM 03-01". The reports are dated 26 October 2018, predating IOM's involvement in the project, and conclude with a 'Certificate of Practical Completion' that indicates MAT were employed by Mercury. The reports were approved by Multiplex and Mercury on 29 October 2018. It is not clear to the Inquiry team why these areas were earmarked for validation. The Inquiry team invite CPs to assist on this point.

4.2.49 It does not appear that the remaining bedrooms in Critical Care were validated, independently or otherwise, prior to IOM's involvement in the project. The involvement of IOM is discussed in Section 5 of this PPP below.

4.2.50 The letter from HFS to NHSL dated 8 March 2019, and referred to at paragraph 4.2.34 of this PPP, also included the following request:

> "Can you therefore please provide evidence of:
> …
> 3. How the Board is assured that the engineering systems are commissioned, validated and set to work to ensure safety, quality and compliance"

4.2.51 NHSL's response of 1 April 2019 provided:

"The Project Agreement including the BCRs are explicit in the need for the engineering systems to be commissioned and validated with respect to safety, quality and compliance. Over and above this core requirement, additional measures have also been implemented including;

The role of the Independent Tester is key to this process. They were required to review 100% of the engineering systems commissioning testing certification for compliance, over and above this, they were required to actually witness first hand 25% percent of the tests, targeting critical systems.

We enclose screenshots of sample lists of certification which was produced by IHSL for the Independent Tester for the purposes of issuing a Certificate of Practical Completion. We also enclose copies of the certificates for specific examples enclosed. As you will see, there is a comprehensive suite of testing and commissioning documentation all of which has been approved and *I* or signed off by the Independent Tester as appropriate.

In addition, during the commissioning phase of the project, the Board's project team with the support of Mott MacDonald also witnessed selective commissioning and testing of specific areas *I* systems in the Facilities.

The Board's Project Team also reviewed the commissioning risk assessments and method statements relative to compliance with guidance."

5. Post-contractual completion events

5.1 On 4 January 2019, NHSL's Head of Commissioning Jackie Sansbury emailed David Wilson, Commissioning Manager for Multiplex. NHSL's Commissioning Manager Ronnie Henderson and the RHCYP/DCN Project Director, Brian Currie were included among the recipients. The email stated:

> "please see the requirements from Dr Inverarity the head virologist for NHS Lothian regarding theatre verification. We insist that the requirements of SHTM 03-01 be met in that Infection Control required a formal validation summary report (and not a collection of documents with uninterpreted particle count and pressure). The non-negotiable expectation from SHTM 03-01."

This text is followed by the following excerpts taken from SHTM 03-01:

> "Ventilation system commissioning/validation report
> 8.64 Following commissioning and/or validation a full report detailing the findings should be produced. The system will only be acceptable to the client if at the time of validation it is considered fit for purpose and will only require routine maintenance in order to remain so for its projected life.
> 8.65 The report shall conclude with a clear statement as to whether the ventilation system achieved or did not achieve the required standard. A copy of the report should be lodged with the following groups:
> - the user department;
> - infection control (where required);
> - estates and facilities.
>
> and UCV validation report
> 8.173 A validation a full report detailing the findings should be produced. The report shall conclude with a clear statement as to whether the UCV theatre suite achieved or did not achieve the standard set out above.

8.174 A copy of the report should be lodged with the following groups:

- operating department;
- infection control;
- estates and facilities."

5.2 On 9 January 2019, Ms Sansbury emailed NHSL's lead infection control doctor, Donald Inverarity, and lead HAI [Healthcare Associated Infection] Scribe advisor, Sarah Jane Sutherland. The email read: "Dear both, re theatre validation. Please see attached the sheet Multiplex intends to complete fro [sic] the theatres. Does this cover all you need?"

5.3 Ms Sutherland responded:

"I have had a look at which guidance relates to Ventilation and note that there is specific guidance within SHTM 03-01 'Ventilation within Healthcare premises' Part A – Design and Validation which outlines the validation and commissioning process (section 8) – I have attached a copy. The contractor/project team should therefore refer to this document to ensure that all the requirements have been met as outlined in the guidance."

5.4 Mr. Inverarity responded:

"Yes I agree, Jackie the validation report should demonstrate that all aspects of SHTM 03-01 have been addressed. This is a much wider exercise than only addressing infection control issues or air testing. The company that performs the validation is expected by SHTM 03-01 (and us) to produce an easy to read succinct report that outlines which aspects have passed or failed, what snagging issues have been identified and how they have been corrected. There is a recent example of such a report from the commissioning of the new theatres at SJH [St. John's Hospital] a couple of years ago."

5.5 Mr Henderson, who had been cc'd to this conversation, then advised:

> "MPX will by handover have carried out all the tests and validation required in the SHTM and will record that they have done so on the master sheet Jackie attached. These results and any commentary will be available as part of the O & M manual, this is in line with all projects carried out in NHSL. This will not be in the form of a specific report. Should we wish to have the validation done independently this can be arranged after handover at a cost to NHSL, however it is worth noting that the company NHSL usually employs to do validation checks of this type is the company carrying out the commissioning on behalf of Multiplex. Happy to meet and discuss so that we can be reassured what is being done meets our needs."

5.6 On 25 January 2019, the Director-General Health & Social Care and Chief Executive sent a letter to NHS Chief Executives. The letter stated:

> "Following…the ongoing incident at the Queen Elizabeth University Hospital (QEUH), I said I would write to you with a set of actions following the meeting of the Strategic Facilities Group on Wednesday 23 January where this issue was discussed at length.
>
> While the cause of the Cryptococcus infections in QEUH is not fully understood at present, and we continue to gather further intelligence on the situation which is resulting in further hypothesises being developed and investigated, there are however, a number of controls that I would like you to confirm are in place and working effectively:
>
> …
>
> - All critical ventilation systems should be inspected and maintained in line with 'Scottish Health Technical Memorandum 03-01: Ventilation for healthcare premises'.

> I have asked Health Facilities Scotland to co-ordinate the responses and would ask that you reply…Friday 1 February."

The Inquiry team have not been able to locate NHSL's response to this request. However, a letter of 31 January from IHSL to Brian Currie responds to the terms of the 25 January letter, confirming that: "all ventilation systems have been designed, installed and commissioned in line with SHTM-03-01 as required". The response does detail the derogations from SHTM 03-01.

5.7 On 11 March 2019 Judith Mackay, Director of Communications, Engagement and Public Affairs for NHSL emailed the project team in anticipation of "questions from the media today about the formal involvement of Infection Control expertise in the design of RHCYP / DCN in the wake of criticisms about the apparent lack of documented evidence of their involvement in the design / commissioning / handover of QEUH".

5.8 Brian Currie responded to this email outlining the involvement of Infection prevention and control (IPC) throughout the project. On 12 March the IPC team's Head of Service, Fiona Cameron, responded directly to Mr Currie:

> "I agree we did have involvement and a dedicate person i.e. our HAI SCRIBE lead involved. However as per communications with Alex [Prof. Alex McMahon, NHSL's Executive Director for Nursing, Midwifery and Allied Healthcare Professionals] IPC were not involved in handover as per SCRIBE guidance recommendations. I cannot reliably say if all our recommendations were accepted".

5.9 That email goes on to raise specific concerns about ventilation:

> "I am aware as a result of the cancelled FOI there was discussion re air exchanges rates perhaps being suboptimal in clinical areas and we don't know what the outcome of that report was. The HAI SCRIBE documents or

minutes of your project meetings should be able to confirm. Another example IPCT can only assume the building engineer who accepted the building on behalf of NHS Lothian saw evidence of theatre validation See p114-124 of SHTM 03-01. IPC to the best of my knowledge have not seen a validation report (section 8.64-8.65 of SHTM 03-01). The validation/commissioning report should be a clearly understood document that outlines that the theatre is working optimally, not just engineering data, which allows us to have confidence in the efficiency of theatre ventilation and would go some way to provide the board with a level of assurance."

The Inquiry team have not been able to identify the "cancelled FOI" referenced by Ms Cameron in her email.

5.10 On 13 March 2019 Donald Inverarity, in an email to Prof. McMahon, adds:

"Although given assurances that pre hand over there would be validation performed on all theatre ventilation, as ICD [Infection Control Doctor] I've never seen any of these validation reports and neither have any of my consultant microbiologist colleagues albeit we were given a tour of the ventilation system and theatres as they were being built. […]

I also mention to you the paediatric isolation rooms which are designed as positive pressure ultraclean rooms with HEPA filtered air and yet the windows open to the outside unfiltered Edinburgh air defeating the purpose of the room. I don't know if any corrective action has taken place regarding this design flaw which was identified by Lindsay, Ewan Olsen and myself when we were invited to review the design of the room and its ventilation pre handover".

5.11 Regarding theatre ventilation validation, Mr Currie wrote:

"Theatre ventilation commissioning, include cascade and UCV validation took place between October 2018 and February 2019 and all certificates and

> reports have been examined and verified by Arcadis as Independent Tester…"

5.12 Mr Inverarity commented on the response from Mr Currie in an email to Prof. McMahon on 15 March:

> "I'm glad there is an independent validation of these results although when the new theatres were commissioned at [St Johns Hospital] in 2017 we were issued with a clear validation report that assured us all was well and functional (attached as an example of the sort of document we were hoping to receive). This is in line with SHTM 03-01 where it states the IPCT can legitimately request the validation report when a theatre is commissioned. I've pasted the relevant section from SHTM 03-01 below":

5.13 Mr Inverarity did not address the issue of air change rates in clinical areas or the "cancelled FOI" any further and concluded the email with:

> "I've spoken with Sarah Sutherland this afternoon and both of us would welcome the opportunity to assist with a walk round as news that the commissioning was complete and the building was now accepted by NHS Lothian had been a surprise to us both".

5.14 On 20 March 2019, an IPC site visit was attended by Mr Henderson, Ms Sutherland and Mr Inverarity. A later email discussing this site visit stated that Mr Henderson and Janice McKenzie [NHSL's Clinical Director]: "felt that the walkround had been arranged specifically to address concerns over water safety and ventilation issues post press articles about QEUH." The email also stated: "Theatre validation was discussed and DI [Donald Inverarity] agreed to forward report from St John's for reference" and that: "RH [Ronnie Henderson] explained the commissioning and validation that had taken place for both isolation rooms and theatres and that records were available on the project data storage system…RH explained that both isolation and theatre validation would be re done once construction works were completed."

5.15 On 27 March, plans were made for the completion of the Stage 4 HAI Scribe review. An email from Donald Inverarity to Sarah Jane Sutherland stated:

> "Hi Sarah,
>
> As part of this can you ensure that for all the isolation rooms in the new building that we are provided with details of the air pressures in the room and anteroom or corridor and ensure that there has been some assessment of air flows and pressures in the room and anteroom, particularly when doors are open. I had been speaking to some of the ID consultants at QEUH and the Glasgow children's hospital yesterday and they explained that all their isolation rooms were being refitted as the original design didn't seem to provide appropriate pressures and air flows when the rooms were occupied".

5.16 Responding to this point, Ronnie Henderson wrote:

> "The system has been designed to ensure the correct airflows and pressures are present at all times however this will need to be confirmed during final commissioning and validation post completion of the works we viewed and discussed last week. If required I can provide the design information that we have available."

5.17 On 10 May 2019 Mr Henderson sent an email to Mr Inverarity attaching a sample 'Theatre Ventilation Validation Checklist' for one of the operating theatres at the hospital. The email stated:

> "Multiplex have provided us with their validation report for Theatre 30 as an example of what they intend to provide for each individual theatre. You will note it differs from the example you sent from St Johns although there is a declaration that it conforms. I can confirm that these have been reviewed and signed off by the independent tester which provides us with reassurance of

compliance. If however you have any doubts or concerns, happy to discuss with a view to appointing someone from outwith the project to give an additional layer of assurance if required."

5.18 Although the attachment to this email is titled 'Theatre Ventilation Validation Checklist', the document relates mostly to commissioning data. The only references to validation are a section headed 'UCV Canopy' which features the entry: "UCV Commissioned & Validated N/A" and a statement reading: "The theatre suite ventilation system has been commissioned and validated in accordance with the required regulations and has achieved the required standard."

5.19 Mr Inverarity's response to this email stated:

"The Multiplex document doesn't indicate what size the theatres are, what the air pressures are in the theatre areas (anaesthetic room, prep area, theatre etc) or what number of air changes per hour are achieved and neither does it mention what, if any, microbiological assessment of air quality has been performed (that box is blank so I'm presuming none has been performed). Although you are being assured that it 'conforms' it isn't explicitly stated what standard it 'conforms' to –presumably SHTM 03-01 ? The statement: 'The theatre suite ventilation system has been commissioned and validated in accordance with the required regulations and has achieved the required standard.' might be factually correct but there is nothing to back it up and it tells us absolutely nothing about how the theatre performs at baseline. It is essentially asking us to taking everything on trust that its all okay. That makes me a little uncomfortable in the current political climate of scrutiny. Does it achieve the required standard with a wide safety margin or did it barely achieve it empty without any operations in progress? At validation the report should tell us at baseline how it actually 'performs' so that if there are problems in the future we have some baseline parameters of air pressures and air changes per hour to compare it against. I see that 'all test documentation is located on Zutec.' I don't know what Zutec is or whether

anyone in NHS Lothian has access to that information so essentially I can't provide any assurance to myself or NHS Lothian by assessing it myself. But in my role as infection control doctor I shouldn't need to go to source documents and extract that information to interrogate and interpret it myself, it should be clearly and explicitly included in the validation report."

5.20 On 13 May 2019, Mr Henderson provided the following response:

"As you know through our previous discussions it is neither our desire nor intention to provide something you are not 100% happy to accept as a suitable record or report. It is true to say that all the relevant information is available on the project data management system 'Zutec', I will ask our AE [Authorising Engineer] (ventilation) to review and independently validate and to provide the type of report you expect. For completeness, I do think it would be beneficial for yourself to view the kind of records held on the Zutec system and I would be happy to demonstrate this say during a one hour session."

5.21 As will be discussed below, the Inquiry team understand that the AE Mr Henderson was referring to in this email was Turner Professional Engineering Services (Turner).

5.22 At an NHSL Programme Board Meeting of 13 May 2019, at which Mr. Henderson was present, it was confirmed that: "RHCYP will open on 9th July 2019 at 08.00hrs, when the existing department will close." The minutes from that meeting do not reflect any discussion of concerns relating to the validation of ventilation equipment.

5.23 On 17 May 2019, Lindsay Guthrie, NHSL's Lead Nurse for IPC, emailed Mr Henderson. The email included the following text:

"I discussed with Donald [Inverarity] the further ventilation validation programme you have arranged for next Friday 24th May. I understand this to

be 1) for theatres, cleaning all ducts, rebalancing and checking pressure cascades, and will not include further UCV testing); and 2) for isolation rooms repeat all commissioning and validation tests

"We do think that it would be useful to have independent validation by an authorising engineer, recognising there is a cost associated with this."

5.24 The same day, Mr Henderson emailed Jamie Minhinnick, an Authorising Engineer at Turner. The email stated:

"We are closing in on the final move date for the new RHCYP & DCN hospital in Edinburgh and the contractor is about to redo validation and commissioning of some ventilation systems. Can I ask the following:

1. Would you be able to come to site on 24/5 to jointly witness the re-validation of Isolation suites, if so I will confirm time and arrangements on Monday after a meeting with the construction commissioning manager.
2. Similarly our Infection Control Team are keen that that the theatres are independently validated and a report produced declaring fitness for purpose, is this a service you can provide/arrange"

5.25 On 20 May, Mr Minhinnick responded:

"I'm afraid I am not available on the 24/5 to witness the isolation rooms. I will speak to my colleagues to see if someone is available.

We do not offer an airflow measurement survey for independent validation. This should be arranged through your verification/validation contractor who will produce a report on the system which I/we can witness and cross reference against the design criteria.

> It is very important at this stage that all commissioning data is made available to your independent validation engineers. All critical systems (as detailed in section 4 of SHTM 03/01 Pt B) should be validated as fit for purpose and to set verification criteria moving forward not just theatres. You should also pass any agreed derogations with regards to ventilation systems to the engineers. Without this, they will be measured against the SHTM03/01 criteria and not the design (which can often be very different)."

5.26 In this email Mr. Minhinnick recommends that NHSL independently validate all critical ventilation systems at the RHCYP/DCN. This appears to reflect the recommendation of SHTM 03-01 discussed at paragraph 3.7.5 of this PPP. A colleague of Mr Minhinnick, Authorising Engineer John Rayner, responded to this email shortly afterward: "I'm afraid that my diary is almost completely full for the next 9 weeks and so I cannot make this last minute commitment for next week."

5.27 Later the same day, Ian Storrar, Head of Engineering at HFS, recommended that Mr Henderson contact BSRAI regarding theatre ventilation verification. On 28 May, Mr Henderson emailed BSRAI. The email included the following text:

> "As part of the initial validation and verification of the various ventilation systems in the new RHCYP/DCN hospital in Edinburgh we require to independently validate our critical systems including theatres and isolation suites as well as radiology areas, is this something you can provide.
>
> Please note there are 10 individual operating theatres and 19 isolation rooms as well as an angiography procedures room and intra-operative MRI
>
> If possible I would like to arrange for this to be done quickly as we are in the process of gearing up to equip these areas for opening which is scheduled for early July."

5.28 In this email Mr. Henderson describes a requirement on NHSL to independently validate all critical ventilation systems at the RHCYP/DCN. This appears to be in response to Mr. Minhinnick's email of 20 May. It is not clear to the Inquiry team why NHSL's references to validation prior to Mr Minhinnick's email are only in relation to theatres and isolation rooms. It is also not clear why NHSL instructed an independent validator in the manner and timeframe set out in these paragraphs. The Inquiry team invite CPs to assist on these points.

5.29 On 30 May, BSRAI advised Mr. Henderson they could not assist. Later that same day, Mr. Henderson emailed IOM. The email included the following text:

> "As discussed we are looking for independent validation to SHTM 03-01 of 10 theatres (7 of which are UCV but can also be used as conventional), 19 isolation rooms, 1 angiography procedures room, 1 intra-operative MRI, and ITU/HDU/NNU. There are also 3 standard MRI's, & 2 CT's, which are non interventional, if these are required under 03-01.
>
> "Due to the large volume I will forward all relevant drawings tomorrow and look to set up an introduction and planning meeting for early next week with a view to carrying the validation out week beginning 17/6."

5.30 IOM's validation commenced on 17 June 2019. The RHCYP/DCN was scheduled to open on 9 July 2019. It is not known whether independent validation at this stage of a project reflects standard or accepted practice.

5.31 An 'RHSC & DCN – Steering Group' meeting note of 24 June 2019 featured the following entry:

> "Critical Ventilation Systems – Independent validation
> - The verification process has highlighted some real concerns with certain areas not achieving the required air changes
> - A separate workstream will look at these questions

- ***Critical to opening****"*

5.32 On 4 July 2019 the decision was taken by Jeane Freeman, the then Cabinet Secretary for Health and Sport, to delay opening the hospital. The Inquiry team understand that test results for the Critical Care department produced by IOM were among the factors that informed this decision. This is, however, subject to further investigation.

5.33 The Inquiry hold 24 'Services Reports' produced by IOM prior to 4 July 2019. At this stage it is not clear if these form the entirety of IOM reports predating that day. The Inquiry team invite CPs to assist on this point.

5.34 Each report indicates that IOM were instructed to validate the hospital's critical ventilation systems on behalf of NHS Lothian. The 'Executive Summary' of each IOM report features the text:

> "SHTM 03-01 requires that critical ventilation systems are validated against design/SHTM standards and that any inability to achieve the recommended standards is classed as a failure."
>
> "This summary highlights where standards have or have not been achieved and is expanded upon in the relevant 'Results' sections."

5.35 The 24 IOM reports investigated 37 areas of the hospital, ranging from UCV theatres to single and four-bed bays in the High Dependency Unit (HDU), isolation suites, recovery rooms and rooms within the neonatal unit. If the 24 IOM reports form the entirety of reports predating 4 July 2019, it is not clear to the Inquiry team why these 37 areas were selected for assessment. The Inquiry team invite CPs to assist on this point.

5.36 Among other things, IOM tested these 37 areas with respect to air change rates and pressure differentials. Of the 37 areas known to the Inquiry team to have

been surveyed, 23 failed to achieve the air change rate and/or pressure differential standards recommended by SHTM 03-01. Of the 23 areas that failed, seven were in Critical Care.

6. Provisional conclusions

6.1 As outlined in the opening pages, this PPP sets out the Inquiry team's initial understanding of the commissioning and validation procedure for the Critical Care areas of the RHCYP/DCN. It is provisional in nature. This PPP does not constitute the findings of the Chair of the Inquiry. It is open to any CP to provide information to assist the Inquiry team and/or contradict the contents of the paper.

6.2 The Inquiry team are of the provisional understanding that:

6.2.1 The Project Agreement provided for Project Co to, as a minimum, commission the facilities in accordance with the 'Guidance to Engineering Commissioning'.[11] The Inquiry team understand that Guidance to outline best practice for all aspects of commissioning. It is therefore understood to be relevant to all parties involved in the project, including NHSL. It is however acknowledged that, so far as the Inquiry team are aware, there was no actual provision for parties other than Project Co to adhere to that Guidance.[12]

6.2.2 That Guidance states that Room Data Sheets should form the basis of commissioning data.[13] The Project Agreement provided for Project Co to commission the systems to comply with the Room Data Sheets.[14] The Room Data Sheets were to include the data contained in the Environmental Matrix.[15] The Inquiry team have not seen any Environmental Matrix or Room Data Sheets post-dating the Settlement Agreement of 22 February 2019, which appears to have effectively finalised the final contractual specification for ventilation.[16]

[11] See para 2.1.4 of this PPP.
[12] See paras 3.1.2 & 3.1.3 of this PPP.
[13] See para 3.2.10 of this PPP.
[14] See para 2.1.2 of this PPP.
[15] See para 4.2.1 of this PPP.
[16] See para 4.2.11 of this PPP.

6.2.3 The Project Agreement also specified that, irrespective of the requirements in the Room Data Sheets, Project Co were to provide mechanical ventilation to suit the functional requirements of each of the rooms.[17] It is therefore not known what the RHCYP/DCN contract intended to be used as the basis of commissioning data for mechanical ventilation. It is also not known what was used as the basis of this commissioning data in practice. The Inquiry team invite CPs to assist on this point.

6.2.4 The essential purpose of ventilation commissioning is to verify that the equipment is capable of delivering the performance criteria required by the design. Ventilation commissioning is not ordinarily concerned with verifying performance criteria against healthcare guidance, although this may be included within the scope of meeting the 'safety requirements' referenced in SHTM 03-01 or the 'user requirements' referenced in SCIM.[18]

6.2.5 The air change rate and room pressure differentials of each area were dictated by the AHU serving that area.[19]

6.2.6 In certain areas noted in Table 1, the air change rate and room pressure differentials were also dictated by a separate IEF.[20]

6.2.7 Each AHU and IEF was commissioned by H&V .[21]

6.2.8 The ventilation equipment relevant to the rooms in Table 1 was commissioned between February and October 2018.[22] However it appears the Settlement Agreement of 22 February 2019 finalised the specification for these rooms, and required an alteration to the design of the four-bed rooms.[23] It is therefore not clear to the Inquiry team how the earlier commissioning sits in relation to the later agreed specification. The Inquiry team invite CPs to assist on this point.

[17] See para 2.1.2 of this PPP.
[18] See para 3.2.8 of this PPP.
[19] See para 4.2.14 of this PPP.
[20] See para 4.2.14 of this PPP.
[21] See para 4.2.15 of this PPP.
[22] See para 4.2.16 of this PPP.
[23] See para 4.2.10 of this PPP.

6.2.9 The 'Guidance to Engineering Commissioning' also states that commissioning should always be completed prior to the issue of a Certificate of Practical Completion.[24] This recommendation appears to have been reflected in the RHCYP/DCN contract.[25] However in practice it appears the Certificate of Practical Completion for the RHCYP/DCN was issued before commissioning of the ventilation systems can have been completed.[26] The Inquiry team invite CPs to assist on this point.

6.2.10 That Guidance also states that ‘Works Staff’ should be involved in the final witnessing and demonstration as part of the familiarisation process.[27] This recommendation was reflected in the Services Contract between IHSL and BYES, who are understood to be the ‘Works Staff’ for the RHCYP/DCN project.[28] However in practice it does not appear that any parties witnessed the commissioning of the AHU relevant to the rooms in Table 1.[29] The Inquiry team invite CPs to assist on this point.

6.2.11 That Guidance also appears to describe CIBSE Commissioning Code A as setting out the ‘systematic set of procedures which must be followed’ when commissioning ventilation systems.[30]

6.2.12 As part of a provision to supply documentation to the IT, the Project Agreement included an expectation that Project Co would provide commissioning documentation in accordance CIBSE Commissioning Code A.[31] The Inquiry therefore understand that the contract expected commissioning to be carried out in a way that reflected the specifics of ‘what should be done’ in the Code. The contract therefore appears to align with the detail of the Code.

[24] See para 3.3.1 of this PPP.
[25] See paras 2.1.14 & 2.1.15 of this PPP.
[26] See para 4.2.18 of this PPP.
[27] See para 3.3.3 of this PPP.
[28] See para 3.3.4 of this PPP.
[29] See Table 1 of this PPP.
[30] See paras 3.3.12 & 3.3.13 of this PPP.
[31] See para 2.1.10 of this PPP.

6.2.13 The Inquiry team understand that measuring air volume flow rates and comparing these with the flow rates required by the design is a crucial aspect of commissioning, as evidenced by CIBSE Commissioning Code A, SHTM03-01 and evidence heard by the Inquiry. The Inquiry team also understand that volume flow rates are required to calculate air changes per hour.[32]

6.2.14 Irrespective of the purpose of commissioning to verify equipment performance against design criteria, the Inquiry team therefore understand that the commissioning phase may have offered an opportunity for the parties involved in commissioning to have sight of design and performance criteria that was later identified by IOM as diverging from healthcare guidance.

6.2.15 It is not clear what individual(s) reviewed test results on behalf of the IT for the rooms in Table 1. The Inquiry team invite CPs to assist on this point. An 'Independent Tester Services' proposal seen by the Inquiry team names John Edwards has having the appropriate capacity to deliver the IT services in relation to Mechanical & Electrical engineering. The proposal also states that Mr. Edwards is a qualified Authorising Engineer for ventilation services. The Inquiry team therefore understand that the IT may have possessed a certain level of awareness and expertise with respect to HTM and SHTM standards. The Inquiry team accordingly understand that this may have offered the IT a greater opportunity to identify design and performance criteria that diverged from healthcare guidance.

6.2.16 Where pressure differentials between areas are intended by a ventilation design, CIBSE Commissioning Code A recommends measuring and recording these between all adjacent spaces, and comparing the measurements with the specified design requirements. The Code states that, once acceptable conditions are obtained, it is imperative to record final balance figures including air volume flow

[32] See pg 17 of the transcript of Mr. Poplett's evidence and Health Facilities Scotland, 'Scottish Health Technical Memorandum 03-01 Ventilation for healthcare premises Part A – Design and validation', (February 2014), para 8.33.

rates and pressure differentials. These should then be verified by the accepting authority.[33]

6.2.17 Although the RHCYP/DCN contract appears to include a provision expecting the detail above to be followed,[34] in practice it appears that no room pressure differentials were recorded, witnessed or approved for the rooms in Table 1.[35] This was despite the design for these areas having pressure requirements relative to adjacent spaces. The Inquiry team invite CPs to assist on this point.

6.2.18 Under the IT Contract, the IT was to review 100% of all Mechanical and Electrical services test results. This is understood to include all the ventilation commissioning test results.[36] It is also understood to align with recommendations in CIBSE Commissioning Code A.[37]

6.2.19 Under the IT contract, the IT was also to issue a Certificate of Practical Completion to the Board and Project Co when he was satisfied that the facilities were complete in accordance with the Completion Criteria.[38]

6.2.20 The Completion Criteria included the provision that all mechanical and electrical plant and systems shall be tested, commissioned and operate satisfactorily in accordance with the specified design criteria and the Room Data Sheets.[39] This too is understood to align with recommendations in CIBSE Commissioning Code A.[40]

6.2.21 In practice it appears the IT issued the Certificate of Practical Completion without room pressure differential data being measured and approved for the rooms in Table 1.[41] This was despite the design for these areas having pressure

[33] See para 3.4.3 of this PPP.
[34] See paras 2.1.10 & 3.4.4 of this PPP.
[35] See Table 1 of this PPP.
[36] See para 2.1.13 of this PPP.
[37] See para 3.4.7 of this PPP.
[38] See para 2.1.14 of this PPP.
[39] See para 2.1.8 of this PPP.
[40] See para 3.4.7 of this PPP.
[41] See Table 1 of this PPP.

requirements relative to adjacent spaces. It is not known why this happened. The Inquiry team invite CPs to assist on this point..

6.2.22 Under the IT contract, the IT was also to issue a Commissioning Completion Certificate on the completion of Project Co's Post-Completion Commissioning and the Board's Post Completion Commissioning.[42] It appears the Commissioning Completion Certificate for the RHCYP/DCN project was issued before commissioning was completed.[43] The Inquiry team invite CPs to assist on this point.

6.2.23 The commissioning of each AHU and IEF by H&V included 'testing and balancing' of these systems. This included measuring air volumes and air velocities. As discussed above, the Inquiry team understand this may have offered an opportunity for the parties involved in commissioning to have sight of air change per hour data that was later identified by IOM as diverging from healthcare guidance.

6.2.24 CIBSE Commissioning Code A provided that, unless the designer specifically called for all commissioning aspects to be witnessed, an assessment of a proportion of results should enable the witnessing authority to establish a level of confidence in the commissioning results being presented.[44] The IT contract envisaged that the IT would witness approximately 50% of the tests for Mechanical and Electrical services such as ventilation systems.[45] However in practice the commissioning of the AHU relevant to the rooms in Table 1 does not appear to have been witnessed.[46] Although the IT does not appear to have witnessed the testing for AHU 04-06, it is not known whether the IT otherwise complied with the witnessing provision in the IT contract.

6.2.25 The Project Agreement provided for Project Co to produce a final draft 'operation and maintenance manual' for the project on or before the day the

[42] See para 2.1.16 of this PPP.
[43] See paras 4.2.19 & 4.2.20 of this PPP.
[44] See para 3.4.5 of this PPP.
[45] See para 2.1.13 of this PPP.
[46] See Table 1 of this PPP.

Certificate of Practical Completion was issued by the IT. The principal version was to be delivered within the next 10 business days. This was to be in sufficient detail to allow the Board to plan for the safe and efficient operation of the facilities.[47] These provisions aligned with recommendations made in SCIM commissioning guidance for contractors to provide operation and maintenance manuals to the client.[48]

6.2.26 The Inquiry team have not been able to locate any final draft or principal operation and maintenance manual for the project. However operation & maintenance manuals for AHUs and fans have been reviewed.

6.2.27 It is not clear if these manuals fulfilled the terms of the Project Agreement for provision of an operation and maintenance manual. It is also not clear if/when these manuals were submitted to NHSL and approved. It is therefore not clear whether the recommendations of the SCIM commissioning guidance were met. The Inquiry team invite CPs to assist on these points.[49]

6.2.28 BYES were trained to operate and maintain the equipment while witnessing equipment tests.[50] Training was subsequently given to NHSL by BYES or Multiplex.[51] For the AHU outlined in Table 1, it does not appear that any equipment tests were witnessed.[52] It is therefore understood that no party was trained to operate and maintain this equipment. It therefore appears that the recommendation in SCIM commissioning guidance, that a facility handover cannot occur without fit-for-purpose and safe operation training,[53] was not met with respect to the AHU in Table 1. The Inquiry team invite CPs to assist on this point.

6.2.29 NHSL secured assurance that adequate operation and maintenance training were provided by reviewing ‘training records’ provided by Project Co. NHSL

[47] See paras 2.1.5 & 2.1.6 of this PPP.
[48] See para 3.5.2 of this PPP
[49] See paras 4.2.42 & 4.2.43 of this PPP.
[50] See para 3.3.5 of this PPP.
[51] See para 4.2.37 of this PPP.
[52] See Table 1 of this PPP.
[53] See para 3.5.1 of this PPP.

were satisfied from these reviews that the appropriate training and certification was in place.[54]

6.2.30 The IT contract provided for the IT to review 100% of all Mechanical and Electrical services test results. This was in alignment with the recommendation in CIBSE Commissioning Code A that commissioning documentation should be provided for the witnessing authority to countersign to confirm test results.[55] The IT approved the AHU commissioning reports for the areas in Table 1.[56] On the basis the commissioning reports show that tests for AHU 04-06 were not witnessed, it is not known why the IT approved these reports. It is also not clear why the IT issued the Certificate of Practical Completion on this basis. The Inquiry team invite CPs to assist on this point.

6.2.31 The Inquiry team also cannot locate commissioning test report approval for any of the IEFs other than for IEF06. On the basis that these reports were not approved, it is not known why the IT did not request the outstanding information for approval or why the Certificate of Practical Completion was issued without this information being approved. The Inquiry team invite CPs to assist on this point.

6.2.32 The essential purpose of ventilation validation is to verify that the system as a whole is fit for purpose. This is understood to mean that validation is, at least in part, concerned with verifying equipment performance criteria against healthcare guidance.[57]

6.2.33 The Inquiry team have been unable to locate any specific provisions for the validation of ventilation equipment in the RHCYP/DCN contract documents. It is not known if this reflected standard or accepted practice at the time the relevant contracts were signed.[58]

[54] See paras 4.2.35 of this PPP.
[55] See para 6.2.18 of this PPP.
[56] See Table 1 of this PPP.
[57] See para 3.6.6 of this PPP.
[58] See para 3.6.1 of this PPP.

6.2.34 In the absence of any contractual provisions, it is assumed that the version of SHTM 03-01 that applied during the construction of the RHCYP/DCN outlined best practice for validation at the time.[59]

6.2.35 That version of SHTM 03-01 recommended that all areas within a hospital requiring specialised ventilation should be validated by an independent party appointed by the Health Board.[60] The areas requiring specialised ventilation included Critical Care areas.[61]

6.2.36 The Inquiry team have seen documents headed with the Multiplex logo, which indicate that single bed isolation rooms were validated on 6 June 2019 and signed off by Multiplex, Mercury and Arcadis.[62] It is not clear from the face of these documents who carried out the validation in relation to the air change rate and room pressure differential data for these spaces. A 'Method Statement for H&V Commissioning Services Ltd' regarding 'Validation of Theatre Suites & Isolation Rooms' has been seen by the Inquiry team, which may suggest that H&V provided the validation, as well as the commissioning, of these rooms. The Inquiry team invite CPs to assist on this point.

6.2.37 It is not clear at this stage why the single bed isolation rooms in Table 1 were validated on 6 June 2019. The Inquiry team invite CPs to assist on this point.

6.2.38 The Inquiry team are aware that UCV theatres at the hospital were validated by MAT on 26 October 2018.[63] This validation was carried out to verify that the installed system performed in accordance with SHTM 03-01. Validation reports produced by MAT were approved by Multiplex and Mercury on 29 October 2018. It is not clear to the Inquiry team why these areas were earmarked for validation prior to IOM's involvement in the project. The Inquiry team invite CPs to assist on this point.

[59] See para 3.6.2 of this PPP.
[60] See para 3.7.3 of this PPP.
[61] See para 3.7.1 of this PPP.
[62] See paras 4.2.44 & 4.2.47 of this PPP.
[63] See para 4.2.48 of this PPP.

6.2.39 The remaining Critical Care areas in Table 1 do not appear to have been validated, independently or otherwise, prior to IOM's involvement in the project.[64] It is not clear why these areas were not included in the validation that appears to have occurred prior to IOM's involvement. The Inquiry team invite CPs to assist on this point.

6.2.40 In March 2019 HFS requested evidence from NHSL as to how the Board was assured that engineering systems including ventilation had been commissioned and validated to ensure safety, quality and compliance. NHSL responded that, among other things, this assurance had been provided by the provisions of the BCRs, the involvement of the IT, and the suite of testing and commissioning documentation approved by the IT.[65]

6.2.41 The Inquiry team are aware that a 'Theatre Ventilation Validation Checklist' for one of the operating theatres at the hospital was shared with infection control prior to IOM's involvement with the project.[66]

6.2.42 On 30 May 2019, IOM were instructed to independently validate the hospital's critical ventilation systems on behalf of NHSL. This step appears to have been taken in response to a recommendation from NHSL's infection prevention control team, after concerns were raised in relation to the 'Theatre Ventilation Validation Checklist' referenced above.[67]

6.2.43 IOM's validation commenced on 17 June 2019. The RHCYP/DCN was scheduled to open on 9 July 2019. It is not known whether independent validation at this stage of a project reflects standard or accepted practice.[68]

6.2.44 In an email to BSRAI, NHSL's Commissioning Manager Ronnie Henderson described a requirement on NHSL to independently validate critical ventilation

[64] See Table 1 of this PPP.
[65] See paras 4.2.50 and 4.2.51 of this PPP.
[66] See para 5.17 of this PPP.
[67] See paras 5.17-5.29 of this PPP.
[68] See para 5.30 of this PPP.

systems at the RHCYP/DCN. This appears to reflect a recommendation in SHTM 03-01, ostensibly brought to Mr Henderson's attention by Authorising Engineer Mr Minhinnick in an email of 20 May 2019.[69] It is not clear to the Inquiry team why NHSL's references to validation prior to Mr Minhinnick's involvement are only in relation to theatres and isolation rooms. It is also not clear why NHSL instructed an independent validator in the manner and timeframe set out in this PPP. The Inquiry team invite CPs to assist on these points.

6.2.45 IOM's validation activities included surveying UCV theatres, single and four-bed bays in HDU, isolation suites, recovery rooms and rooms within the neonatal unit.[70] It is not clear why these specific areas were highlighted for assessment. The Inquiry team invite CPs to assist on this point.

6.2.46 Of the 37 areas known to have been surveyed by IOM, 23 failed to achieve the air change rate and/or pressure differential standards recommended by SHTM 03-01. Of these 23 areas, seven were in Critical Care.[71]

6.2.47 Test results for the Critical Care department produced by IOM were among the factors that informed the decision to delay opening the hospital.[72]

6.2.48 It is possible that, if independent validation had been carried out sooner than June 2019, divergences between the performance of the ventilation equipment in Critical Care and the recommended standards in SHTM 03-01 would have been detected earlier.

[69] See paras 5.25 to 5.28 of this PPP.
[70] See para 5.35 of this PPP.
[71] See para 5.36 of this PPP.
[72] See para 5.32 of this PPP.

7. Questions & requests for documents

7.1 Do you agree with the provisional conclusions of this paper? If not please provide correction or clarification.

7.2 Are you able to provide the following documentation:

- Room pressure differential test data, and IT approval of this, for AHU 04-06 and IEF03 – IEF06;
- Any documentation illustrating that commissioning tests for AHU 04-06 were witnessed; and;
- IT approval of commissioning tests for IEF03 – IEF05.

7.3 If applicable, please explain why room pressure differential tests were not conducted for AHU 04-06 and IEF03 - IEF06, and why commissioning tests for AHU 04-06 were not witnessed.

7.4 If room pressure differential tests were not conducted for AHU 04-06, why did the IT issue a Certificate of Practical Completion and Commissioning Completion Certificate?

7.5 If commissioning tests for AHU 04-06 were not witnessed, why did the IT approve the commissioning reports for AHU 04-06?

7.6 If no Room Data Sheets were produced reflecting the final agreed environmental information, how did paragraph 3.6.3 of the BCRs apply to the project?

7.7 With respect to paragraph 3.6.3 of the BCRs, what did the Board intend to be used as the basis for the ‘functional requirements’ of mechanical ventilation?

7.8 Why were the Certificate of Practical Completion and Commissioning Completion Certificate issued on 22 February 2019, when the commissioning and validation process was not yet complete?

7.9 Prior to IOM involvement, why was validation planned and/or sought for some areas such as single bed isolation rooms and UCV theatres, and not for others?

7.10 Why did NHSL not instruct an independent validation of the RHCYP/DCN's critical care ventilation systems before a recommendation to do so was made by the infection prevention and control team on 17 May 2019?

7.11 With respect to performance parameters, was the ventilation equipment serving critical care commissioned against a standard other than SHTM 03-01? If so, what was this standard?

7.12 With respect to performance parameters, was the ventilation equipment serving critical care validated against a standard other than SHTM 03-01? If so, what was this standard?

7.13 The Inquiry hold IOM surveys predating 4 July 2019 for the following rooms: 1-B1-009, 1-B1-031, 1-B1-063, 1-B1-037, 1-B1-065, 1-B1-075, 1-B1-016. Please provide any remaining IOM surveys conducted for the Critical Care department prior to 4 July 2019 and which were available at the time the decision was taken to delay the opening of the hospital.

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